



SIONC PHARMACEUTICALS PVT. LTD.
Factory: Plot No. 34A, Road No. 1, JN Pharma City, Parawada, Thanam,
Visakhapatnam-531021, Andhra Pradesh, India, Ph: +91-8924-236117/236118,
Fax: +91-8924-236119, E-mail: info@sioncpharma.co.in

CERTIFICATE OF ANALYSIS

Name of the Product	: ISOTRETINOIN	Page No.	: 1 of 3
Batch Number	: 2013/3/003/13	A.R.No	: FP/2013/13/03/008
Manufacturing Date	: 27/03/2013	Expiry / Re-test Date	:
Batch Quantity	: 8.100 Kg	Dispatch Quantity	: ---
Customer Name	: ---	Date of Analysis	: 09/04/2013

S. No.	Test Parameter	Specification	Result
1.0	Description	Yellow to light orange, crystalline powder	Light orange, crystalline powder
2.0	Solubility	Soluble in Chloroform, sparingly soluble in Ethanol, in Isopropyl alcohol and in Polyethylene glycol 400, practically insoluble in Water.	Complies
3.0	Identification by		
	a) IR	The IR spectrum of the sample should match with the standard.	Complies
	b) HPLC	The retention time of the major peak in the chromatogram of the test solution should correspond to that of the standard solution in assay by HPLC.	Complies
	c) UV absorption at 354nm (On dried basis, %)	Absorptivities at 354nm do not differ by more than 3.0	1.46
4.0	Loss on Drying (16 hours at 27±2°C under Vacuum, % w/w)	Not more than 0.1	0.14

Compiled by	Checked by	Approved by
<i>ee</i> 22/11/2012	<i>Manmull</i> 22/11/2012	<i>Manmull</i> 22/11/2012
G.Ravi Kumar	D. Subba Rao	R.Manmadha Rao
Sr.Executive -QC	Dy. Manager	Asst. Manager - QA

Office Address: Regd. Off: #43-11-56, Subbalakshmi Nagar, Railway New Colony, Visakhapatnam-530016, Andhra Pradesh, India, Ph: +91-891-2712885, Fax: +91-891-2712875.

FM01/QA035/01-01/02/2013



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S. No.	Test Parameter	Specification	Result
5.0	Heavy Metals (ppm)	Not more than 20	Less than 20
6.0	Residue on Ignition (%w/w)	Not more than 0.1	0.06
7.0	Related substances by HPLC (%w/w)		
	a) Impurity-A	Not more than 0.5	0.04
	b) Epoxy	Not more than 0.2	0.07
	c) 11, 13 di cis retinoic acid	Not more than 0.2	Not Detected
	d) Any unknown impurity	Not more than 0.1	0.01
	e) Total Impurities before main peak	Not more than 0.7	0.08
	f) Total Impurities after main peak	Not more than 1.0	0.04
8.0	Assay by Titrimetry (On dried basis, % w/w)	Not less than 98.0 and Not more than 102.0	99.9
9.0	Assay by HPLC (On dried basis, % w/w)	Not less than 98.0 and Not more than 102.0	99.4
10.0	Residual solvents by GC (ppm)		
	a) Methanol	Not more than 3000	Not Detected
	b) Acetone	Not more than 5000	1678
	c) Acetonitrile	Not more than 410	Not Detected

Compiled by G.R. 22/11/2013 G.Ravi Kumar Sr.Executive -QC	 Checked by D.V. Subba Rao Dy.Manager-QC	Approved by Mamall 22/11/2013 R.Manmadha Rao Asst.Manager - QA
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S. No.	Test Parameter	Specification	Result
	d) Methylene Chloride	Not more than 600	Not Detected
	e) n - Hexane	Not more than 290	Not Detected
	f) Ethyl acetate	Not more than 5000	Not Detected
	g) Tetrahydrofuran	Not more than 720	Not Detected
	h) n-Heptane	Not more than 5000	Not Detected
	i) Triethylamine	Not more than 320	Not Detected

REMARKS : The material complies as per the USP/In-house specification.



Compiled by	Checked by	Approved by
ER 22/11/2013	Devi 22/11/2013	Manmadha 22/11/2013
G.Ravi Kumar	D.V.Subba Rao	R.Manmadha Rao
Sr.Executive -QC	Dy.Manager-QC	Asst.Manager - QA

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